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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,422	09/08/2006	Boris Schwartsburd	057878-000024	8394
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DAVID S. RESNICK NIXON PEABODY LLP 100 SUMMER STREET BOSTON, MA 02110-2131				
EXAMINER				
KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
09/12/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/567,422

Applicant(s)

SCHWARTSBURD ET AL.

Examiner

CHIH-MIN KAM

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-20 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-20 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-12, 15-20 and 46 are pending.

Applicants' amendment filed June 2, 2008 is acknowledged. Applicants' response has been fully considered. Claims 1, 9, 11, 16 and 18 have been amended, claims 13, 14 and 42-45 have been cancelled, and a new claim 46 has been added. Thus, claims 1-12, 15-20 and 46 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 13, 14 and 42-45 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' cancellation of the claims in the amendment filed June 2, 2008.
3. The previous rejection of claims 1-20 and 42-45 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at page 6 in the amendment filed June 2, 2008.

Withdrawn Claim Rejections - 35 USC § 102

4. The previous rejection of claims 42-43 under 35 U.S.C. 102(b) as being anticipated by Kim *et al.* (PNAS 97, 1190-1195 (Feb 2000)), is withdrawn in view of applicants' cancellation of the claims, and applicants response at page 6 in the amendment filed June 2, 2008.
5. The previous rejection of claims 42 and 45 under 35 U.S.C. 102(b) as being anticipated by Gerdy *et al.* (WO 01/04276), is withdrawn in view of applicants' cancellation of the claims, and applicants response at page 7 in the amendment filed June 2, 2008.

6. The previous rejection of claims 42 and 44 under 35 U.S.C. 102(b) as being anticipated by Revel *et al.* (WO 99/02552), is withdrawn in view of applicants' cancellation of the claims, and applicants response at page 7 in the amendment filed June 2, 2008.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-12, 15-20 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-12, 15-20 and 46 are directed to a method of purifying or capturing a non-immunoglobulin protein of interest having between one and ten immunoglobulin-like (Ig-like) domains from a biological fluid, comprising the steps of: contacting the biological fluid containing the protein of interest with an Hydrophobic Charge Induction Chromatography (HCIC) resin, washing out the resin to remove unbound contaminants, and eluting the protein of interest by treating the resin with a solution having an acidic pH or with a solution comprising an organic solvent; and to specific proteins of interest.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical

genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification describes the use of specific HCIC resin such as MEP-HyperCel and propylene glycol as the organic solvent at a concentration between 25 and 50% in the method of purifying specific non-immunoglobulin proteins having between one and ten immunoglobulin-like (Ig-like) domains (pages 5-7), the specification does not disclose a genus of variants for HCIC resins and organic solvents used in the claimed method. Furthermore, the specification has not identified any other HCIC resins and organic solvents used in the claimed method, nor has described the effects of using the variants. A single species of HCIC resin such as MEP-HyperCel and a single species of organic solvent such as propylene glycol (at concentration of 25 and 50%) used in the claimed method (Examples 1-4, 8 and 9) do not provide sufficient written description for the genus of variants for HCIC resins or organic

solvents, when there is substantial variation in the whole genus. The lack of description of using various HCIC resins and organic solvents in the claimed method, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate what is well known in the art does not have to be described in the specification. (MPEP 2163, II, A2). It is well known to a skilled artisan that Burton was the first to describe and name the Hydrophobic Charge Induction Chromatography (HCIC) (Burton et al., 1998). Thus a skilled artisan, at the time of filing the present application, was well aware that HCIC is based on the pH-dependent behavior of a dual-mode, ionizable ligand, and that the ligand contains structural features to support hydrophobic binding (see, e.g., Schwartz et al., 2001, Exhibit A). Based on this description, a skilled artisan would have known what different variations of the resin and solvents would be possible for variations of the general concept of HCIC. Accordingly, the claims fully comply with 35 U.S.C. 112, first paragraph, written description requirement, and that the rejection should be withdrawn (pages 6-7 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because while the concept of HCIC and the ligands containing structure features used in the HCIC are known to a skilled artisan, it is not known that HCIC with various resins having different ligands (e.g., amine ligands or carboxylic ligands) and various organic solvents are applicable for purifying a non-immunoglobulin protein having one to ten Ig-like domains. The specification merely describes the use of specific HCIC resin such as MEP-HyperCel and

propylene glycol as the organic solvent at a concentration between 25 and 50% in purifying a non-immunoglobulin protein having between one and ten immunoglobulin-like (Ig-like) domains. Furthermore, Schwartz et al. (2001, Exhibit A) indicates the HCIC sorbent described in the paper carries a ligand (i.e., MEP HyperCel) that is antibody-selective, and this sorbent can be effectively used in purification of antibodies (page 252, left column, first paragraph; right column, third paragraph). Therefore, without providing sufficient teachings on the use of HCIC with various resins and various organic solvents for the claimed method, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms. Therefore, the rejection is maintained.

Conclusion

8. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

September 9, 2008